REMARKS/ARGUMENTS

Status of the Claims

Upon entry of the present amendment, claims 84-92 are pending.

Claim 84 is amended to set forth that the concentration of sialyltransferase is at least 2 mUnit/mg of glycoprotein acceptor. Support is found, for example, on page 23, lines 5-6.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 84-92 are rejected under 35 U.S.C. § 112, second paragraph for alleged indefiniteness.

Sufficient time and under appropriate conditions

The Examiner objects to the phrase "sufficient time and under appropriate conditions." Specified ranges of time, temperature, pH, and salt conditions sufficient to carry out the present methods are described in the specification on page 17, lines 3-24. Further, Applicants set forth concentration ranges for enzyme and glycoprotein acceptor in the claims. Based on the disclosure of the specification and language of the claims, those of skill in the art would readily recognize the metes and bounds of sufficient time and appropriate conditions for carrying out the claimed methods.

mUnit

Applicants confirm that the abbreviation "mUnit" is in accordance with what the Examiner acknowledges is generally understood in the art to mean "milliUnit," or 1000th of one unit of enzyme. *See*, page 3 of the present Official Action. Applicants define unit on page 16, line 30 through page 17, line 2 of the specification. As set forth in the specification, one activity Unit catalyzes the formation of 1 μmol of product per minute at a given temperature (typically 37°C) and pH value (typically 7.5).

In view of the foregoing, those of skill would recognize the metes and bounds of the claimed methods. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Rejection under 35 U.S.C. § 112, first paragraph, enablement

Claims 84-89 and 92 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabled. Applicants do not agree with the Examiner. However, in the interest of furthering prosecution, Applicants have amended claim 84 to set forth that the concentration of sialyltransferase is at least 2 mUnit/mg of glycoprotein acceptor. To the extent that this rejection applies to the amended claims, this rejection is respectfully traversed.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). *See also, United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). Further, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). *See also*, M.P.E.P. § 2164.01. Also, the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). *See also*, M.P.E.P. § 2164.08.

Here, Applicants teach on page 23, lines 5-6 that the present methods can be successfully carried out using at least 2 mUnit/mg of sialyltransferase per glycoprotein acceptor.

The Examiner appears to agree that the present specification enables a method using a *Campylobacter jejuni* α2,3-sialyltransferase in a reaction mixture comprising at least 2 mUnit/mg of sialyltransferase per glycoprotein acceptor. *See*, page 4 of the present Official Action.

Applicants respectfully submit that it was well within the capability of one of ordinary skill in the art to test various concentrations of enzyme and glycoprotein acceptor within the ranges taught and claimed to optimize a desired sialyltransferase reaction. This well known approach is also taught on page 11, lines 26-29 of the specification. Those of skill in the art would expect to prepare a matrix of different reaction mixtures with varying concentrations of enzyme and acceptor to optimize a desired sialyltransferase reaction. The Examiner concedes that it is routine in the art to perform enzyme assays as encompassed by the instant claims. *See*, page 5 of the present Official Action. Moreover, Applicants teach and claim a range of enzyme and glycoprotein acceptor concentration ratios wherein those of skill in the art could apply them with a reasonable expectation of success and without undue experimentation (*e.g.*, 1-100 mUnit/mg protein, 2-50 mUnit/mg protein; *see*, page 11, lines 26-29 and page 23, lines 4-6). Because claim 84 sets forth a minimum ratio of enzyme to glycoprotein receptor (*i.e.*, at least 2 mUnit/mg protein), those of skill in the art could determine without undue experimentation an appropriate concentration of glycoprotein acceptor in a reaction mixture volume to successfully carry out the present methods without undue experimentation. At the time of the January 1997 priority date of the present application, those of skill could readily recognize that if the glycoprotein acceptor is too dilute, the enzyme will not efficiently sialylate the acceptor. Likewise, if the glycoprotein acceptor is too concentrated, the glycoprotein acceptor is likely to precipitate out of solution.

In view of the foregoing, Applicants teach those of skill in the art how to carryout the claimed methods without undue experimentation. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Non-Statutory Double Patenting

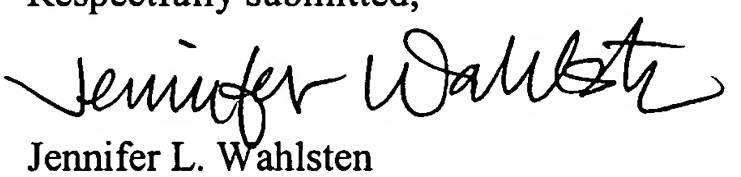
The Examiner has rejected claims 84-92 under the judicially created doctrine of double patenting as allegedly obvious over various claims in U.S. Patent No. 6,399,336. In response, Applicants stand ready to file an appropriate Terminal Disclaimer once the outstanding rejections are resolved.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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Attachments
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